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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/100,516	06/19/1998	LARRY V. KASTER JR.	3038240/5847	8642

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EXAMINER

KRUSE, DAVID H

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 08/28/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/100,516

Applicant(s)

KASTER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 18 April 2002 has been entered.

Status of the Application

2. Claim 1 has been amended as requested and claims 12-20 and 24 have been cancelled.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claim 1 is objected to because of the following informalities:

At line 5 of step (i), the word "carrier" should read -- carry --.

At line 2 of step (ii), the word "resistance" should read -- resistant --.

Claims 2-11 and 21-23 are objected to because the phrase "A method according to claim 1" should read -- The method according to claim 1 --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1, 2-11 and 21-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Accordingly claims 2-11 and 21-23 are indefinite because the limitations in said claims do not obviate the indefiniteness of claim 1 as follows;

At claim 1, the preamble is directed to a method of producing a transgenic plant, while in neither of the method steps is there a recitation of a transgenic plant, hence it is unclear how the transgenic plant is produced. See MPEP § 2172.01.

At line 3 of step (i), the phrase “an advanced vegetative state” is relative and does not state the metes and bounds of the claimed method. Applicant states on page 3, lines 11-12, that “an advanced vegetative state” is relative to the plant, “depending upon the pollen development”, but Applicant does not teach how pollen development is to be interpreted in view of “an advanced vegetative state” in relation to any plant.

At line 4 of step (i), the phrase “herbicide effectively inhibits pollen” is indefinite because it is unclear from the specification what the metes and bounds of this limitation are. The specification teaches selectively inhibiting production of pollen lacking an herbicide resistance transgene of a heterozygous transgenic plant comprising said herbicide resistance gene so that heterozygous plants do not produce pollen lacking said herbicide resistance transgene within a population of plants. Hence, it does not appear that Applicant intends to claim an herbicide that would actually inhibit pollen, but

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that said herbicide would inhibit pollen production from a susceptible plant because said plant is heterozygous for the herbicide resistance transgene. Clarification is required.

At line 1 of step (ii), the term "obtaining" is indefinite because it is unclear what the metes and bounds of this limitation are in relation to the claimed method and the teachings of the specification. It is suggested that the term -- identifying -- or -- isolating -- be used. In addition, the phrase "herbicide resistance progeny" does not agree with the preamble of the claim.

At claim 2, line 1, the phrase "herbicide resistant plants" lacks a proper antecedent basis in claim 1. In addition, at line 2, the phrase "stage (i)" lacks a proper antecedent basis in claim 1, and appears to be further limiting method step (i).

At claim 9, the phrase "trait comprises a high oil system" is indefinite because the claim is further limiting "a quality trait" encoded by a gene and the phrase appears to be directed to many quality trait genes that comprise a high oil system. Hence, it is unclear what the metes and bounds of this claim are.

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3-11, 21 and 22 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic maize plant comprising applying glyphosate to a population of transgenic plants wherein said glyphosate inhibits pollen lacking a transgene that confers glyphosate resistance on said transgenic plant, does not reasonably provide enablement for a method of

producing any transgenic plant comprising any transgene conferring resistance to any herbicide upon said transgenic plant. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims a method of producing a transgenic plant which shows herbicide resistance to a herbicide by applying said herbicide to a population of progenitor plants such that the applied herbicide effectively inhibits pollen which does not carry the herbicide resistant gene and obtaining resistant progeny.

Applicant teaches a method of producing a transgenic maize plant comprising applying glyphosate to a population of transgenic, glyphosate resistant maize plants at an advanced vegetative state before flowering and obtaining herbicide resistant progeny (see Example 2 on pages 11-12 of the specification).

Applicant does not teach a method of producing a transgenic plant comprising applying an herbicide other than glyphosate to a population of transgenic plant as broadly claimed.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant provides limited guidance for practicing the claimed method, providing guidance only for use of the herbicide glyphosate and glyphosate resistant-transgenic plants. It was known in the art at the time of Applicant's invention that glyphosate, and closely related compounds, has gametocide activity, and can be used to produce male sterility in plants (see Dhingra *et al*, U.S. Patent 4,735,649, see whole document). Conversely, many herbicides were known in the art at the time of Applicant's invention, yet Applicant provides no guidance as to which known herbicides have gametocide activity or guidance for how to make transgenic plants tolerant of such herbicides. The art teaches other herbicide resistance genes such as cytochrome P450 monooxygenases, which confer resistance to several classes of herbicides, for example phenylurea herbicides (see Siminszky *et al* 1999, Proc. Natl. Acad. Sci. USA 96:1750-1755). Yet Applicant provides no guidance for the use of phenylurea herbicides as gametocides or transgenic plant resistant to phenylurea herbicides by which one of skill in the art could practice the claimed method. The nature of the art appears to be such that one of skill in the art must identify both an herbicide having gametocide activity and a method of producing a transgenic plant tolerant of said herbicide in order to practice the method of the instant invention as broadly claimed. Hence, given the limited guidance by Applicant, the teaching of the art at the time of Applicant's invention and the nature of the invention, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to screen through a myriad of herbicides to identify those that have gametocide activity, isolate genes conferring

tolerance to the identified herbicides, and produce transgenic-herbicide tolerant plants to practice the invention as broadly claimed.

Claim Rejections - 35 USC § 103

9. Claims 1-11 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer *et al* (U.S. Patent 6,040,497) in view of Dhingra *et al* (U.S. Patent 4,735,649). This rejection has been modified from the rejection of the previous Office action mailed 5 July 2001.

Spencer teaches a method comprising the steps of applying the herbicide glyphosate to a population of glyphosate resistant corn plants at the vegetative stages comprising V1 through V10, encompassing the limitation of "at an advanced vegetative state before flowering" where said plants produce viable pollen to fertilize female plants and obtaining progeny therefrom. Spencer further teaches that the progeny plants derived from those treated with glyphosate are glyphosate resistant. Additionally, Spencer teaches the introduction of the GA21 transgene into both inbred and hybrids and the introduction of the GA21 event into multiple lines via breeding, and the introduction of one or more transgenes comprising a GA21, GJ11, GG25 or FI117 transformation event. Furthermore, at the time of Applicant's invention many single gene traits, which can be transformed into plants, were known in the art. Examples of such traits include, but are not limited to, male sterility, waxy starch, herbicide resistance, male fertility, and enhanced nutritional quality.

Spencer does not teach the use of glyphosate as a gametocide.

Dhingra teaches that glyphosate can be used as a gametocide to selectively produce male sterility.

Hence, the claims would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention in view of the teachings of Spencer and the teachings of Dhingra. Dhingra teaches the inherent gametocide property of glyphosate and thus when one of ordinary skill in the art would be motivated to practice the method of Spencer, the use of glyphosate, especially at an advanced vegetative state, would inherently act as a gametocide and produce the claimed method.

See MPEP 2112 which states that the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of non-obviousness should be commensurate with the scope of the claims.

Applicant argues that Spencer neither teaches nor suggests spraying the progeny at any specific level or stage of growth and that the concept is not taught nor suggested by the prior art (see page 2 of the Remarks). The Examiner responds that the instant claims are not directed to a specific level of herbicide or stage of growth *per*

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se, but state general limitations such as "advanced vegetative state" and "wherein the applied herbicide effectively inhibits pollen which does not carrier the herbicide resistant gene". Also, Spencer at column 51 teaches the application of glyphosate at stage V5-V8 as encompassed by claim 5. In addition, the instant rejection has been modified to address the issues of the teachings of Spencer.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Kim Davis whose telephone number is (703) 305-3015.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

**AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

David H. Kruse, Ph.D.
22 August 2002